IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Ethicon") submit this reply brief in further support of their motion to exclude certain general opinions of Daniel Elliott, M.D.

I. The Court should limit Dr. Elliott's product warning opinions.

After devoting nearly four pages to bashing Ethicon for supposedly filing a brief that is duplicative of its briefs from prior waves, Plaintiffs object to Ethicon's challenge of Dr. Elliott's warning opinions on the basis that Ethicon did not challenge those opinions in prior waves. Plaintiffs do not explain how Dr. Elliott's qualifications as it relates to this topic are any different than the qualifications of all of the other urogynecologists whose opinions the Court has limited in this litigation. Consistent with the way the Court has treated all other similarly-situated clinician experts, Ethicon requests that the Court allow Dr. Elliott to "testify about the specific risk of implanting mesh and whether those risks appeared on the relevant IFU," but preclude him from testifying "about what information should or should not be included in an IFU." *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582220, at *3 (S.D. W. Va. Sept. 1, 2016).

II. The Court should preclude Dr. Elliott from testifying that non-synthetic mesh procedures are a safer alternative.

Plaintiffs correctly note that, in prior waves, this Court stated that it would consider Ethicon's challenges to Dr. Elliott's opinions about non-synthetic mesh procedures on a "case-by-case basis." *See In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500766, at *4 (S.D.W. Va. Aug. 26, 2016). Plaintiffs, however, fail to acknowledge that, since that time, this Court has: (a) found that such challenges should not be raised in case-specific motions, *Brooks v. Ethicon, Inc.*, No. 2:12-cv-02865, Mem. Op. at 4 (S.D.W. Va. July 12, 2017) (Ex. K to Doc. 4364); and (b) issued a blanket exclusion of such opinions from another expert pelvic surgeon (*In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017)).

Regardless of which state's law applies, Dr. Elliott—as with Dr. Goodyear—should never be allowed to suggest that traditional surgical procedures are safer alternatives to the devices at issue. These are medical device cases, not medical malpractice cases. Plaintiffs wish for the juries in these cases to conclude that a device can be found defective if the physician should have performed a different kind of surgery instead. But a device case is about devices, not surgeries. If there is no better way to make the device, then the choice of surgeries is up to the surgeon. *Theriot v. Danek Medical Inc*., 168 F.3d 253, 255 (5th Cir. 1999) (rejecting claim that pedicle screws were defective because a different surgery could have been performed: "The problem with this argument is that it really takes issue with the choice of treatment made by Theriot's physician, not with a specific fault of the pedicle screw sold by Danek").

The choice of a surgery or treatment is up to the surgeon. And here the implanting surgeons deliberately chose for their own reasons not to use the alternatives that Dr. Elliott advocates.

Moreover, the fact that Ethicon has advocated surgery using the devices at issue as a more permanent alternative to traditional surgeries—which have their own unique complications, such as a high failure rate—does not make a comparison between the two the standard for deciding design defect. In the pedicle screw cases, Danek no doubt believed that pedicle screws were better than other surgical choices. A manufacturer is entitled to have opinions about medical procedures and to offer physicians a choice which juries should not be able to take away without evidence that the medical device could have been made in a safer way.

So if a plaintiff wants to invoke an alternative to impeach an existing "product," it necessarily must be another "product." Otherwise, the courts are comparing apples to oranges, not to other apples. For example, it is one thing to compare TVT to a similar minimally-invasive device with a low failure rate, but it is quite another to compare it to Burch colposuspension using no mesh but having a higher failure rate, especially when the success of either procedure will depend, among other things, on the experience and skill of implanting surgeon. That is a comparison for the surgeon to make, not the court.

This is a specialized application of a more general principle in product liability law that is not dependent on a state having a strict safer alternative design requirement. For example, in *Driesenstok v. Volkswagenwerk, A.C.*, 489 F. 2d 1066, 1074 (4th Cir. 1974), an unreasonable risk case, the court held that a Volkswagen bus could not be found to present an unreasonable risk just because it was less crashworthy than a sedan, because the two served their own "peculiar purposes." And in *Linegar v. Armour of Am. Inc.*, 909 F.2d 1150, 1154 (8th Cir. 1990), the court held that, for the purposes of an "unreasonably dangerous" claim under RESTATEMENT (SECOND) OF TORTS §402A, a bullet proof vest could not be faulted just because it

covered less than a bullet-proof jacket. Each served its own purposes although one alternative was manifestly safer than the other is some situations.

In a similar vein, the existence of an entirely different drug combination cannot make a drug defective even if they treat the same disease. *Brockert v. Wyeth Pharms., Inc*., 287 S.W.3d 760, 770-771 (Tex. App. – Houston 14th Dist. 2009). And on the other side is a case that endorses this same principle – alternatives must have the same "fundamental characteristic" – but found that a jury in a negligence case could find that to be true where the alternatives were either a lower dose or a natural version of the same drug. *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D.W.Va. 2010). That is nothing like this case. As the Illinois federal district court said, distinguishing *Torkie-Tork*, here "the gap between the mesh product at issue here and a distinct surgical procedure is too large to merit submission to a jury." *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *3 n.3.

For these reasons, if a plaintiff wants to prove unreasonable danger by resorting to evidence of an alternative design, it has to be an alternative design of the same device, and not a different kind of device, and certainly not a different surgery, or treatment. Each of them serves its own "peculiar purposes," *Driesenstok, supra*, or has its own "fundamental characteristics." *Torrkie-Tork, supra*. It does not matter whether or not safer alternative design is a requirement in the jurisdiction. *See* Ex. A, Drug and Device Law Blog, "On Alternative Design, Take Two – Negligence" (Feb. 27, 2017) (discussing relevance of alternative design even absent statutory requirement). What matters is that the plaintiffs seek to prove their case by offering evidence of a safer alternative in order to prove liability, and what the liability is based on, whether it be unreasonable danger, negligence, or strict liability, does not matter.

The "peculiar purpose" of Ethicon's devices was to reduce the risk of surgical failure and to enable a particular kind of surgery. Traditional surgical procedures, such as native tissue surgery, do not serve either of those purposes and so cannot be considered a safer alternative for the purposes of product liability law. And given the vast numbers of patients successfully treated with Ethicon's products, there can be no claim—regardless of which state's law applies—that the product is so egregiously dangerous that it never should have been put on the market. *In re Alloderm(r) Litig.*, 2015 WL 5022618 (N.J. Super. L. Aug. 14, 2015) (no egregious danger where hernia graft was admittedly useful in a subset of patients).

III. The Court should preclude Dr. Elliott from comparing TVT Secur with other medical devices.

For the same reasons set forth above, the Court should not allow Dr. Elliott to suggest that TVT, TVT-O and/or other devices were safer, feasible alternative devices to TVT Secur. Further, given Dr. Elliott's unequivocal testimony that he does not believe that synthetic mesh should be placed in the vagina, it is unreliable and inappropriate for him to suggest to the jury that another product containing synthetic mesh is a viable alternative.

IV. The Court should preclude Dr. Elliott from testifying that a device with lighter weight, larger pore mesh would serve as a safer alternative.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section II of Doc. 3029.

V. The Court should preclude Dr. Elliott from criticizing the cut of TVT mesh.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section III of Doc. 3029.

VI. The Court should not allow Dr. Elliott to speculate about the duties of a medical device manufacturer.

Regardless of what state law applies, Plaintiffs have failed to demonstrate how Dr. Elliott has requisite competence to provide expert opinions regarding the alleged duty of a medical device manufacturer as it relates to premarket testing/studies, adverse event reporting, and physician training. Accordingly, the Court should exclude all of these opinions.

VII. The Court should preclude Dr. Elliott from testifying about alleged mesh degradation, shrinkage, contraction, and other biomaterials opinions.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section V of Doc. 3029.

VIII. The Court should prevent Dr. Elliott from providing general opinions about TVT Exact.

Plaintiffs have agreed that "Dr. Elliott will not offer any opinions regarding the TVT-Exact device." Doc. 4558, Pl's Resp. at 15.

IX. The Court should not allow other opinions beyond Dr. Elliott's expertise and/or that are otherwise improper.

Ethicon adopts its Wave 3 reply argument on this issue set forth in Section VI of Doc. 3029.

CONCLUSION

For the foregoing reasons and those set forth in Ethicon's prior briefing, the Court should limit Dr. Elliott's testimony in these cases.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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